JUN 2 3 2000

K001142

section 10: 510(K) SUMMARY

510(K) Summary of Safety and effectiveness

Trade name:	Audio Prosthesis- Audio Technologies
Common name:	Prothesis for othosurgery
Classification name:	Partial Ossicular Replacement Prosthesis Total Ossicular Replacement Prosthesis
submitter:	AUDIO TECHNOLOGIES S.r.l. Via Vallera 9 I-29100 – PIACENZA - Italy
Official contact:	contact person: dr. Franco Beoni (general director) telephone: +39/0523/778864 fax number: +39/0523/770019 e-mail: audiotechnologies@tin.it
Date prepared:	May 16th, 2000

predicate devices:
The *Audio Prosthesis - Audio Technologies*, are substantially equivalent to *Richards - marketed by Smith & Nephew*, and/or *Xomed - marketed by Xomed*, and/or *Exmoor - marketed by Exmoor Plastics.*

description:
otosurgical prosthesis of the middle ear, implanted, in a permanent manner, in patients affected with pathologies of the middle ear.
otosurgical prosthesis of the middle hear, are manufactured from a wide variety of materials: platinum (Pt), titanium, poliethylene (PE), stainless steel, hydroxylapatite (HA), politetrafluoroethylene (teflon, PTFE), gold and polimetilxilossano (silicon), or combination of these materials.
Numerous designs are available for replacement of any or all of the bones of the ossicular chain.

intended use:
for replacement for any or all of the bones of the ossicular chain in the middle ear

indications for use

Audio prostheses are successfully employed in case of otosclerosis, stapedo-vestibular ankylosis, outcome of otitis media, trauma, middle ear congenital malformations. Possible complication due to the use of prostheses in the middle ear include: fixation, displacement, extrusion of the prosthesis, incus necrosis, tympanic membrane perforation, perilymph fistula, labyrinthitis, otitis media, occlusion of oval and round window.
Some of the prostheses are maufactured in different lenghts, some others shall be trimmed during the surgical oparation. Nevertheless the lenght of all the prostheses should be carefully assessed by means of a microsurgical gauge (code 02.14)

Warning: Ref. TAP 07.18 – PAP 07.19
After taking the distance by means of the gauge TPL 02.14, use a prosthesis having the same lenght: the telescopic movement makes the insertion under the hammer handle easier. Do not implant prostheses which are not fully extended. If the implanted prosthesis is still a little compressed, it can exert an excessive pressure on the stapes and cause dislocation or break.

comparison to predicate devices:
These devices have the same indications for use (Partial / Total Ossicular Replacement Prosthesis, for reconstruction of the ossicular chain that has lost its function, due to disease, trauma, or congenital defect), the same technological characteristics, i.e. materials (all widely accepted for middle ear reconstruction), and the same general design.
Slight design differences between Audio Technologies Prosthesis and the predicate devices should not affect the safety and effectiveness

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 3 2000

Dr. Franco Beoni
Audio Technologies
Via Vallera 9
Piacenza, Italy
9-29100

Re: K001142
Trade Name: Total/Partial Ossicular Replacement Prostheses
Regulatory Class: II
CFR: 874.3450 and 874.3495
Product Code: 77ETB and 77ETA
Dated: May 18, 2000
Received: May 22, 2000

Dear Dr. Beoni:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

- statement of indication for use

otosurgical prosthesis of the middle ear, implanted, in a permanent manner, in patients affected with pathologies of the middle ear.
Are used for different types of otosurgery, such as stirrup bone surgery (otosclerosis, stapedioplasties), chronic middle ear disease (tympanoplasties and total replacement of middle ear).
The implant must be carried out by a qualified surgeon.

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K001142